

### **REMARKS**

Claims 23, 25-26, and 28-29 are currently pending. Claims 23, 26, 28, and 29 have been amended. The specification has been amended to address several informalities objected to by the Examiner. None of the amendments constitute new matter.

The Examiner has objected to the information disclosure statement filed on August 20, 2003. The Examiner objects to the specification due to the inclusion of an imbedded hyperlink, and the format of Figure 4.

The Examiner has rejected claims 23, 25, 27, and 29 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has rejected claims 23, 24, 26, 27, and 29 under 35 U.S.C. § 112, first paragraph, for lacking support in the written description. The Examiner has rejected claims 23, 25, 26, and 28 under 35 U.S.C. § 112, second paragraph, as indefinite. For the reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

#### **Information Disclosure Statement**

The Examiner has objected to the information disclosure statement filed on August 20, 2003 for failing to include copies of references previously submitted in related applications. In order to expedite the prosecution of this matter, Applicants enclose a Supplemental Information Disclosure Statement and copies of the references in question.

#### **Objections To The Written Description**

The Examiner objects to the specification due to the inclusion of an imbedded hyperlink, and the format of Figure 4. The specification has been amended to delete reference to the

imbedded hyperlink, and to amend the pages of Figure 4 to recite 4A and 4B. The specification has also been amended to reflect the new labeling of Figure 4.

### **The Claims Are Enabled**

The Examiner has rejected claims 23, 25, 27, and 29 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states that the amino acid sequence encoded by the claimed nucleic acid sequence “does not correspond to a glutamate-gated chloride channel” but is instead “the amino acid sequence of a **subunit** of a glutamate-gated chloride channel that is capable of functioning as a homo-pentameric structure composed of five identical subunits.” (Emphasis in original).

Applicants note that claim 27 has been canceled, and therefore the rejection with regard to claim 27 is moot.

Applicants note that claims 23, 26, and 29 have been amended to recite that the “lepidopteran glutamate-gated chloride channel is comprised of polypeptides encoded by a nucleic acid sequence which is at least 90% homologous to the nucleic acid sequence ~~encoded by~~ of nucleotides 144 through 1484 of SEQ ID NO:13.” Support for this amendment can be found in the specification at pages 5, lines 5-21 and at page 24, lines 24-27. Claim 23 has also been amended to recite “wherein a change in the flux of chloride is indicative of an agent that modulates activity.” Support for this amendment can be found in the specification at, for example, page 10, line 22 to page 11, line 6 and claim 26 as originally filed. Applicants submit that based upon the disclosure in the specification, a person of ordinary skill in the art would understand that the subunits encoded by nucleotides 144 through 1484 of SEQ ID NO:13 would be capable of forming a lepidopteran glutamate-gated chloride channel. For example, the

specification discloses that the sequence designated HEGE2, which includes the coding sequence for the polypeptide, forms a functional lepidopteran glutamate-gated chloride channel when introduced into *xenopus* oocytes. See the specification at, for example, pages 22-26, in particular at page 24, lines 26-27. As noted by the Examiner, the lepidopteran glutamate-gated chloride channels are known to be formed from a homo-pentameric structure. Lastly, the specification provides methods for the identification of functional activity of the lepidopteran glutamate-gated chloride channel. See the specification at, for example, page 9, line 8 to page 10, line 9.

Based upon the disclosure in the specification and the knowledge of a person of ordinary skill in the art at the time of filing as cited by the Examiner, a person of ordinary skill in the art would understand that the “polypeptide encoded by a nucleic acid sequence which is at least 90% homologous to the nucleic acid sequence of nucleotides 144 through 1484 of SEQ ID NO:13” would be capable of forming a lepidopteran glutamate-gated chloride channel, and would be capable of identifying nucleic acids of sufficient homology with no more than routine experimentation. The specification also provides ample guidance for a person of ordinary skill in the art to determine whether the lepidopteran glutamate-gated chloride channel has functional activity with no more than routine experimentation. Accordingly, a person of ordinary skill in the art is enabled by the specification to generate the lepidopteran glutamate-gated chloride channel and practice the present invention.

Applicants submit that the claims, as amended, are enabled, and respectfully request withdrawal of the rejection.

**The Claims Are Supported By The Written Description**

The Examiner has rejected claims 23, 24, 26, 27, and 29 under 35 U.S.C. § 112, first paragraph, for lacking support in the written description. The Examiner states that “the majority of protein embodiments meeting the limitation of ‘is at least 90% homologous to the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO:13’ are synthetic proteins and not ‘lepidopteran’ in origin.” The Examiner further states that “the specification describes only a single species of the claimed genus” which is insufficient to constitute a representative number of species within the genus.

Applicants note that claim 27 has been canceled, and therefore the rejection with regard to claim 27 is moot.

Applicants assert that the specification clearly provides ample written description of the claimed genus. Even where only one species is disclosed, the written description requirement may be satisfied by providing “functional characteristics coupled with a known or disclosed correlation between function and structure.” MPEP § 2163. In particular, Applicants assert that the specification provides ample disclosure regarding the structural feature of sequence homology, which is coupled to the known function of glutamate-gated chloride channel activity.

The specification clearly provides a common structural feature in the form of a nucleotide sequence, *i.e.*, nucleotides 144 through 1484 of SEQ ID NO:13. In addition, the specification clearly envisions the use of sequences which are at least 90% homologous to the disclosed nucleic acid sequences, and provides for methods of identifying homology. See the specification at, for example, page 5, lines 5-12. As discussed above, it is well within the abilities of a person of ordinary skill in the art to identify sequences of sufficient homology. The specification also discloses that the amino acid sequence encoded by the nucleic acid sequence comprising

nucleotides 144 through 1484 of SEQ ID NO:13 has lepidopteran glutamate-gated chloride channel activity, and provides data regarding the expression of functional lepidopteran glutamate-gated chloride channels in *xenopus* oocytes. See the specification at, for example, pages 9, line 8 to page 10, line 9, and at pages 22-26. Accordingly, a person of ordinary skill in the art is provided with ample disclosure of a common structural feature of the genus, *i.e.*, homology to the identified sequence, which is correlated to a known functional characteristic, *i.e.*, glutamate-gated chloride channel activity. Thus, a person of ordinary skill in the art would be capable of identifying other members of the claimed genus based upon homology to the recited sequence and the presence of glutamate-gated chloride channel activity. Accordingly, the claimed genus is fully described by the specification.

Furthermore, Applicants assert that the term “lepidopteran” does not limit the claimed polypeptides merely to those of lepidopteran origin. The specification defines the phrase “lepidopteran glutamate-gated chloride channel” to encompass polypeptides and proteins produced via recombinant, *i.e.*, synthetic, methods and polypeptides encoding nucleic acids homologous to the reference lepidopteran sequence (which may not be, strictly speaking, lepidopteran themselves). See the specification at, for example, page 8, line 21 to page 9, line 3. Accordingly, the phrase “lepidopteran glutamate-gated chloride channel” is clearly supported by the specification.

Based upon the foregoing, Applicants assert that the claims are fully supported by the specification, and respectfully request withdrawal of the application.

**The Claims Are Definite**

The Examiner has rejected claims 23, 25, 26, and 28 under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner states that

“the limitation ‘wherein said lepidopteran glutamate-gated chloride channel is at least 90% homologous to the sequence...’ is illogical. In the art of molecular biology the term ‘homology’ refers to similarities between analogous features from different entities.”

The Examiner also states that the recitation of “the sequence encoded by nucleotides 144 through 1484 of SEQ ID NO:13” is materially the same as the recitation of “the amino acid sequence of SEQ ID NO:14.”

Applicants note that claims 23 and 26 have been amended to recite that the claimed sequence is “at least 90% homologous to the nucleic acid sequence ~~encoded by~~ of nucleotides 144 through 1484 of SEQ ID NO:13.” Accordingly, claims 23 and 26 now recite that the homology of the sequences is between nucleic acids, and accordingly is comparing analogous features.

In addition, Applicants assert that these amendments address the Examiner’s concern regarding the difference between nucleotides 144 through 1484 of SEQ ID NO:13 and SEQ ID NO:14. As amended, claims 23 and 26 now recite a nucleic acid sequence (nucleotides 144 through 1484 of SEQ ID NO:13) whereas claims 25 and 28 now recite an amino acid sequence (SEQ ID NO:14). As such, the claimed subject matter of these claims are distinct.

Based upon the foregoing, Applicants assert that the claims are definite, and respectfully request that the rejections be withdrawn.

**CONCLUSION**

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicant believes that the inventions described and defined by claims 23, 25-26, and 28-29 are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Respectfully submitted,



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